IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

UNITED STATES OF AMERICA Plaintiff, v. SAGE PHARMACEUTICALS, INC. a corporation, and JIVN REN CHEN, and CHARLES L. THOMAS, individuals Defendants.	CIVIL NO. 13-cv-1983

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Honorable Court as follows:

Introduction

1. This action is brought by the United States of America (hereinafter "Plaintiff") pursuant the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to enjoin and restrain Sage Pharmaceuticals, Inc., a corporation ("Sage"), and Jivn Ren Chen and Charles L. Thomas, individuals (hereinafter, collectively, "Defendants") from violating:

a. 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce any new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

b. 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce any article of drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

c. 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

Jurisdiction and Venue

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b).

Defendants

4. Defendant Sage is incorporated under the laws of Louisiana, and does business at 5408 Interstate Drive, Shreveport, LA 71109, within the jurisdiction of this Court. Sage manufactures, processes, labels, holds, and distributes drugs.

5. Defendant Jivn Ren Chen is the President of Sage. He is responsible for overseeing the overall operations of Sage, including sales, manufacturing, quality assurance, and finances. He has the duty, power, and responsibility to prevent, detect, and correct violations.

6. Defendant Charles L. Thomas is the Director of Corporate Quality at Sage. He is responsible for establishing and maintaining the quality assurance system at the firm. He has been present at all FDA inspections, and a regulatory meeting where unapproved new and misbranded drugs were discussed. He also has the duty, power, and responsibility to prevent, detect, and correct violations.

7. Defendants have been and are now engaged in the business of manufacturing, processing, packing, labeling, holding, and distributing in interstate commerce several products,

including pain relievers, cough and cold remedies, and topical wound cleansers that are drugs within the meaning of 21 U.S.C. § 321(g).

Defendants' Violations

8. Defendants' products are drugs within the meaning of 21 U.S.C. § 321(g) because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and/or are intended to affect the structure or any function of the human body.

9. Defendants regularly manufacture drugs using components they receive in interstate commerce and introduce finished drug products into interstate commerce for shipment outside the state of Louisiana.

9. The United States Food and Drug Administration ("FDA") inspected Defendants' facility most recently between February 14 - 17, 2012 ("February 2012 Inspection").

10. The February 2012 Inspection revealed that Defendants manufacture and distribute into interstate commerce the following drug products:

a. Relagesic, which is a prescription pain reliever;

b. Ru-Hist D tablets and Ru-Hist D liquid, which are over-the counter ("OTC") cough and cold remedies; and

c. Septicare Wound Cleanser and Deodorant ("Septicare") and Perifoam Anti-Bacterial Cleanser ("Perifoam"), which are topical skin cleansers.

11. During the February 2012 Inspection, FDA investigators also observed that Sage had manufactured Nu-COPD and Ru-Hist Plus, two OTC cough and cold remedies, but had not yet distributed these products. Defendant Thomas stated that Sage planned to distribute all inventory on site.

12. During the February 2012 Inspection, Defendants also stated that they were no longer manufacturing the pain reliever Dolorex. However, when FDA returned to collect samples in June 2012, investigators found that Sage manufactured Dolorex in March 2012.

Defendants' Products are Unapproved New Drugs

13. Defendants have been and are now engaged in the manufacture, processing, packing, labeling, holding, or distributing of numerous unapproved new drugs that they introduce or cause to be introduced into interstate commerce, in violation of 21 U.S.C. § 331(d). These unapproved new drugs include, but are not limited to: Relagesic, Dolorex, Ru-Hist Plus, Ru-Hist D tablets, Ru-Hist D liquid, Nu-COPD, Septicare, and Perifoam.

14. FDA has conducted a search of its records for New Drug Application ("NDA"), Abbreviated New Drug Application ("ANDA"), and Investigational New Drug Application ("IND") submissions by Defendants. FDA has ascertained that Defendants have no approvals on file of an NDA, ANDA, or IND for any of the eight drugs listed above.

15. A "new drug" is defined as any drug "the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1).

16. For a product to be deemed "generally recognized as safe and effective" ("GRAS/GRAE"), it must: (1) have substantial evidence of safety and effectiveness, or (2) if it is an OTC drug, comply with a monograph established pursuant to an FDA regulation. 21 U.S.C. § 355(d); 21 C.F.R. § 330.1.

17. Based upon searches of the publically available medical and scientific literature, FDA has determined that there are no published adequate and well-controlled investigations or

any other scientific literature demonstrating that Defendants' drug products are GRAS/GRAE for any use. Because there are no adequate and well-controlled investigations of the intended use of these drugs, qualified experts cannot come to a consensus of opinion concerning the effectiveness of Defendants' drugs. Therefore, these drugs are not GRAS/GRAE, and are new drugs under the Act.

18. Also, a drug product may be deemed GRAS/GRAE, and thus marketed without an approved NDA, ANDA, or IND application, if the drug is manufactured and distributed in strict compliance with an OTC monograph. 21 C.F.R. § 330.1. With respect to OTC drugs, FDA has reviewed the active ingredients and the labeling for over 80 therapeutic classes of drugs. For each of these categories, FDA has published an OTC drug monograph in the Federal Register. OTC drug monographs clearly identify acceptable ingredients, doses, formulations, and labeling for specific active ingredients used in OTC drug products.

19. Defendants' two OTC topical wound cleansers, Septicare and Perifoam, do not conform to any OTC monograph set forth in 21 C.F.R. § 330.1.

20. Although there are monographs for cold/cough remedies—see 21 C.F.R. Part 341, Cold, Cough, Allergy, Broncho-dialator, and Antiasthmatic Drug Products for Over-the-Counter Human Use—none of Defendants' four OTC cough and cold drug products conform to it.

21. For example, Ru-Hist D tablets, Ru-Hist D liquid, and Ru-Hist Plus contain a nasal decongestant—phenylephrine hydrochloride—and an antihistamine—pyrilamine maleate. Under the applicable OTC monographs, phenylephrine hydrochloride is to be taken every 4 hours, see 21 C.F.R. § 341.80(d)(1), and pyrilamine maleate is to be taken every 6-8 hours, see 21 C.F.R. § 341.72(d)(11). Thus, Ru-Hist D tablets, Ru-Hist D liquid, and Ru-Hist Plus cannot meet the applicable OTC monographs because there is no way to write adequate directions for

use that would be meet the dosage interval requirements for each of the active ingredients according to their respective monographs.

22. In addition, Nu-COPD does not meet the applicable monographs for its active ingredients, phenylephrine hydrochloride, see 21 C.F.R. § 341.80(d)(1), and guaifenesin, see 21 C.F.R. § 341.76(d). Both ingredients' monographs require dosing every four hours, and Nu-COPD's label states that the product can be dosed every four to six hours.

23. Accordingly, by manufacturing and distribution these unapproved new drugs, Defendants introduce unapproved new drugs, or cause them to be introduced, into interstate commerce, in violation of 21 U.S.C. § 331(d).

Defendants' Products Are Misbranded Drugs

24. A drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use." Pursuant to 21 C.F.R. § 201.5, "adequate directions for use" are defined as "directions under which the layman can use a drug safely and for the purpose for which it is intended." Adequate directions for use must be based on animal and clinical data derived from extensive, scientifically controlled testing.

25. It is not possible to write such directions for Defendants' drugs listed above, because adequate directions for drug use—including indications, contraindications, dosages, routes of administration, warnings, side effects, and necessary collateral measures—are necessarily premised on animal and clinical data derived from extensive, scientifically controlled testing.

26. Defendants do not have any well-controlled clinical test data for the eight drugs listed above. Consequently, adequate directions under which a layman can safely use these drugs cannot be written. Moreover, because the products at issue are unapproved new drugs, as

described above, these drugs are not exempt from the requirement for adequate directions for use—21 C.F.R. §§ 201.100(c)(2), 201.115.

27. Furthermore, Ru-Hist D tablets, Ru-Hist D liquid, Ru-Hist Plus, and Nu-COPD are misbranded because the dosage intervals provided on their labels do not strictly adhere to the dosage intervals listed in the relevant FDA OTC monographs.

28. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

29. Defendants violate 21 U.S.C. § 331(k), by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

History of Violations

30. Defendants are aware that their conduct violates the law and that continued violations could lead to regulatory action.

31. In 1998, the United States of America sought to enjoin Sage for violations of FDA's current good manufacturing regulations and for distributing unapproved new drugs.

32. In 2000, as a result of that injunction action, the Court issued an order, requiring Sage to cease manufacturing and distributing two specific unapproved new drugs at issue in that case—Palgic D and Palgic DS—until FDA approval of an NDA for those products.

33. Since the entry of that order, Defendants have refused to cease manufacturing and distributing other unapproved new and misbranded drugs, despite various warnings from FDA.

34. FDA has issued repeated warnings over the last thirteen years during in-person meetings and in written letters. Defendants have responded to the agency's letters and meetings

with promises to stop manufacturing certain unapproved products, promises to file applications for approval for specific products; and claims that FDA is incorrect about the interpretation of its regulations.

35. At a prior FDA inspection between May 2-6, 2011, FDA investigators informed Defendants that they were distributing unapproved new and misbranded drugs. Defendants did not respond orally to this information at the May 2011inspection. In their written responses to the May 2011 inspection, however, they stated that they would cease manufacturing and distributing Relagesic.

36. At the February 2012 Inspection, the FDA investigator collected evidence that Defendants continued to manufacture and distribute Relagesic.

37. During the February 2012 Inspection, Defendants stated that they no longer manufactured Dolorex.

38. When FDA returned to collect samples in June 2012, investigators found that Sage had manufactured Dolorex in March 2012.

39. FDA informed Defendants that they are manufacturing and distributing unapproved new and misbranded drugs in letters dated January 13, 2012, December 14, 2011, September 28, 2011, November 21, 2007, August 28, 2007, January 29, 2007, and June 23, 1999. Several of those letters specifically state that Septicare and Relagesic are unapproved new drugs.

40. Defendants also received a Warning Letter dated October 11, 2002 that warned Defendants that the extended release guaifenesin tablets they were manufacturing at the time were unapproved new drug products that could be subject to an enforcement action.

41. The agency also held meetings with Defendants on September 15, 2011, July 31, 2000, and January 13, 2000 to discuss the firm's manufacture and distribution of unapproved new and misbranded drugs, including Septicare, Relagesic, and Perifoam.

42. Although Defendants stopped manufacturing particular products, such as the products that were the subject of the previous injunction and the October 11, 2002 Warning Letter, they began manufacturing different unapproved new and misbranded drugs to take the place of the discontinued products.

43. As demonstrated by the results of FDA's most recent inspection, Defendants continue to violate the Act, by inter alia continuing to manufacture Septicare, Relagesic, and Perifoam, despite numerous warnings from FDA that these products are illegal.

44. Based on Defendants' course of conduct throughout the past thirteen years and the results of FDA's inspections, Plaintiff is informed and believes that, unless restrained by order of this Court, Defendants will continue to distribute unapproved new and misbranded drugs in violation of the Act, 21 U.S.C. § 331(a) and (d), and to cause drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 331(k).

Prayer for Relief

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin, pursuant to 21 U.S.C. § 332(a), Defendants, and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive notice of the Court's order, from doing or causing to be done, any of the following acts:

A. Violating 21 U.S.C. § 331(d) by distributing unapproved new drugs in interstate commerce;

B. Violating 21 U.S.C. § 331(a) by distributing misbranded drugs in interstate commerce; and

C. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

II. Order Defendants, and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive notice of the Court's order, to cease manufacturing and distributing any drug product unless and until:

A. An approved new drug application or abbreviated new drug application pursuant to 21 U.S.C. § 355(a) or (j) is in effect for the product; or

B. An investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or

C. The product is manufactured and distributed in strict compliance with an OTC monograph set forth in 21 C.F.R. § 330.1; and

III. That Plaintiff be granted judgment for its costs herein, including costs of investigation to date, and that this Court grant such other and further relief as it deems just and proper.

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DATED this 20th day of June, 2013

Respectfully Submitted,

OF COUNSEL:

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH DICKINSON
Associate General
Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel,
Litigation

TARA BOLAND
Associate Chief Counsel
United States Department of
Health and Human Services
Office of the General Counsel
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
Phone: (301) 796-8549

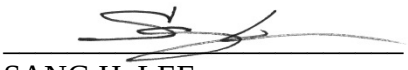
STEPHANIE A. FINLEY
United States Attorney

KATHERINE W. VINCENT
Assistant U.S. Attorney, Civil Chief

RAMSAY MCCULLOUGH
No. 802717
Assistant U.S. Attorney
300 Fannin St., Suite 3201
Shreveport, LA 71101
Phone: 318-676-3600

STUART F. DELERY
Acting Assistant Attorney General

MAAME EWUSI-MENSAH FRIMPONG
Deputy Assistant Attorney General
Civil Division
U.S. Department of Justice



SANG H. LEE
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
Civil Division
P.O. Box 386
Washington, DC 20044
Phone: (202) 514-0516
E-mail: Sang.H.Lee@usdoj.gov